Rapid ART: Rapid Initiation of Antiretroviral Therapy Protocol for Newly Diagnosed HIV Positive Adults

Contra Costa Health Services

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**Purpose:**

Currently in Contra Costa County, 30% of newly diagnosed HIV positives are not linked to care within 30 days, the time from diagnosis to initiation of antiretroviral therapy (ART) averages many months, and there are additional months before they achieve virologic suppression. During this time period between positive diagnosis and treatment initiation, these HIV-positive individuals remain potentially at risk for spreading HIV to others via sexual contact or intravenous drug use. Eliminating the HIV epidemic in the county and in the U.S. requires addressing this population and shortening the window of time during which newly-diagnosed individuals are at risk for transmitting HIV to others. A recent study found that among heterosexual couples, viral suppression (defined as less than 200 copies of HIV virus per mL of blood) reduced the risk of sexually transmitting the virus to an uninfected partner by 96%.[[1]](#footnote-1) Although 87% of HIV positives in Contra Costa County are aware of their HIV+ status, only 70% are on antiretrovirals and virally suppressed. In 2014, 104 people were newly diagnosed with HIV in Contra Costa County. Initiation of Rapid ART is now recommended to be offered to newly diagnosed HIV-positive individuals as an effective means to close this gap of diagnosed but not virally suppressed individuals.[[2]](#footnote-2)

**Background:**

San Francisco piloted a rapid initiation of antiretroviral therapy protocol in 2013. The goal was to reduce the time from diagnosis to initiation of ART from weeks/months to hours/days. They initially targeted new patients with acute HIV infection, and then extended the protocol in 2014 to include all new diagnoses of HIV. They were able to reduce the mean time of ART initiation from 37 days to 1 day, and the time from diagnosis to viral load suppression from 132 days to 56 days. Patient acceptance was high, with 99% of patients offered Rapid ART still taking ART 60 days after ART initiation versus only 80% offered ART via traditional approach.[[3]](#footnote-3) They are now expanding their Rapid ART protocol to include all testing and treatment sites within the City and County of San Francisco by 2020.

**Outcome Goals of Rapid ART:**

Delivering (ART) as soon as possible after diagnosis:

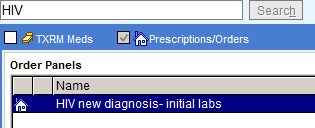
1. Improves morbidity and mortality in all stages of infection;[[4]](#footnote-4)
2. In acute/recent HIV infection: limits reservoirs and hyper-infectivity;[[5]](#footnote-5)
3. Reduces transmission by 96%;[[6]](#footnote-6) and
4. With use of currently available antiretroviral regimens poses a very low risk of developing antiretroviral resistance when ART is started while awaiting results of resistance testing and modifying therapy once resistance test results are known.[[7]](#footnote-7)

**Process Goals of Rapid ART:**

1. The Contra Costa County HIV/AIDS Program is informed of all new positive patients on the same day of their diagnosis (see protocol below for paging) to support insurance and medication access navigation.
2. All newly diagnosed HIV-positives are navigated to a Positive Health Clinic within 7 days of confirmed diagnosis.
3. Positive Health Providers start ART on the first visit.
4. Hospitalized patients start ART before they are discharged from the hospital (consider consulting positive health clinic clinicians for advice on regimen selection).

**Services to Prove Upon Diagnosis (by clinician)**:

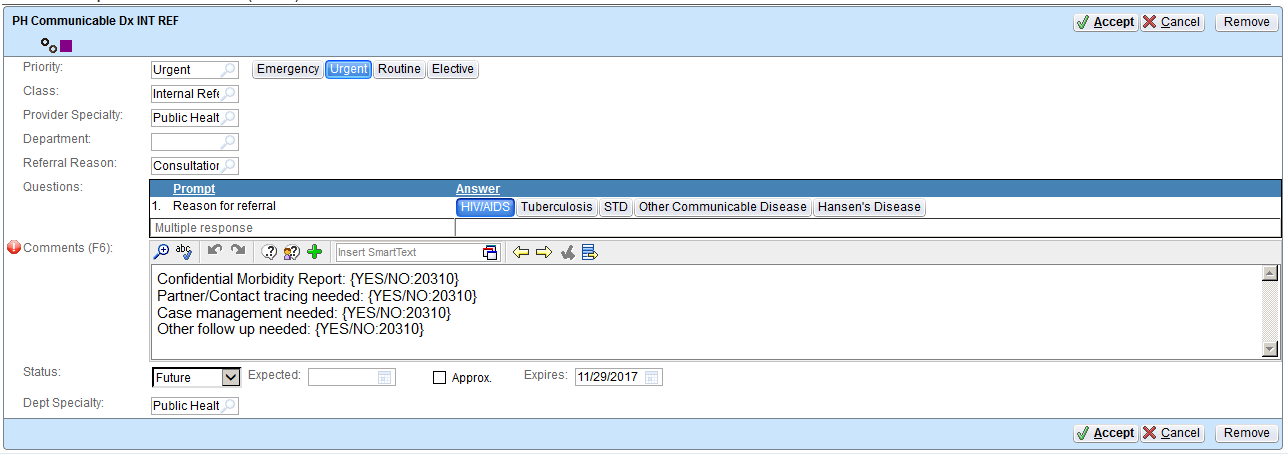
1. Disclosure of positive HIV test result
2. Counseling
3. Benefits/Insurance navigation, including plan for medication access (HIV/AIDS Program can assist—see below for process):
   1. Emergency ADAP (AIDS Drug Assistance Program)
   2. Presumptive Medi-Cal
4. Linkage to HIV outpatient care (Positive Health Clinic) within 7 days
5. Medical evaluation including baseline labs (“HIV New Diagnosis Initial Labs” panel), which includes: T cells, HIV quantitative RNA, comp panel, HLA B5701, chronic hepatitis panel, CBC/d, RPR, toxo IgG, urinalysis, microalbumin/creatinine ratio, quantiferon-TB, HIV genotype. Labs should be drawn before patient takes their first dose of ARVs. ARV initiation can begin before results are available.



1. Immediate ART initiation at first Positive Health Clinic visit (or in hospital if admitted)
2. Check in with patient 1-2 days after ART initiation by phone/text/email by clinician/social worker/case manager
3. Clinician schedules follow-up appointment for 1 week after ART initiation

**Engaging HIV/AIDS Program Case Management to Provide Support:**

After providing test result disclosure and post-test counseling, clinicians should call the Contra Costa Public Health HIV/AIDS Program at 925-313-6771 from 8:00 am-5:00 pm, M-F. Ask to speak with the “Social Worker of the Day” who will process the referral. *If time sensitive follow up is required indicate specifically what is needed or what barriers to HIV care exist.* For results that come in during off hours, use the Public Health Communicable Disease Internal Referral system:



Effort should be made to inform the HIV/AIDS Program as soon as possible and to do a warm handoff. A key role of the Contra Costa HIV/AIDS Program is to ensure that patients receive individualized post-test counseling and education. This includes but is not limited to discussion of the patient’s new HIV diagnosis, psychosocial assessment/intervention, discussion of risks/benefits of treatment, education on HIV and safer sex practices. Outreach Workers then assess patients for potential barriers to successful linkage to care (medical insurance including drug benefits, mental health, substance use, unstable housing, and legal challenges). Specifically, the HIV Program may:

1. Support patient in processing HIV test result
2. Enroll patient to Ryan White-funded medical case management/wrap around support services (i.e. food Bank, counseling, legal support, medical transportation)
3. Enroll patient to ADAP (AIDS Drug Assistance Program) and/or OAHIPP (Office of AIDS Health Insurance Premium Payment) to ensure medication affordability
4. Enroll patients who are not eligible for insurance in HIV ambulatory care coverage through Ryan White
5. Support patient to disclose HIV result to partners and provide information on pre-exposure prophylaxis (PrEP) with Truvada for partners
6. Provide risk reduction information
7. Communicate with pharmacy to ensure patient can access supply of ART
8. Schedule patient into Positive Health Clinic
9. Remind patient of upcoming appointments
10. Meet patient at follow up appointments

**Who is Eligible for Immediate ART?**

1. Anyone with a new, confirmed HIV diagnosis unless there is a clear contraindication to starting immediate ART
2. Known HIV-positives who are hospitalized and previously not engaged in care and not on ART with a clear, uncomplicated ART history that suggests a low likelihood of ART resistance should start ART while in the hospital once they are stable and tolerating oral meds

**Who is Not Eligible for Immediate ART?**

1. Persons for whom immediate ART might be medically dangerous and who should undergo a thorough evaluation and stabilization before ART:
   1. Individuals with untreated cryptococcal meningitis should defer ART for 5 weeks after the diagnosis and antifungal treatment initiation
   2. Individuals with pulmonary or gastrointestinal Kaposi’s sarcoma before chemotherapy (usually Doxil) has been started
   3. Individuals with active Tuberculosis should consider deferring ART for 5 weeks after the diagnosis and anti-TB treatment initiation and consult with TB program staff

**Recommended Rapid ART regimens:**

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| --- | --- | --- | --- |
| ***Regimen*** | ***Pill Burden*** | ***Pros*** | ***Cons*** |
| dolutegravir (Tivicay) 50mg once daily  tenofovir alafenamide 25mg/emtricitabine 200mg (Descovy) once daily | 2 pills once daily | -Rapid drop in viral load  -Well tolerated  -High barrier to resistance  -Once daily dosing | Limited experience |
| darunavir (Prezista) 800mg once daily  ritonavir (Norvir) 100mg once daily  tenofovir alafenamide 25mg/emtricitabine 200mg (Descovy) once daily | 3 pills once daily | -High barrier to resistance  -Clinical experience suggests efficacy even if M184V mutation present  -Once daily dosing | Drug interactions (ritonavir a CYP3A4 inhibitor) |
| raltegravir (Isentress) 400mg twice daily  tenofovir alafenamide 25mg/emtricitabine 200mg (Descovy) once daily | 1 pill twice daily  +  1 pill once daily | -Rapid drop in viral load  -Well tolerated | BID dosing |
| Tenofovir alafenamide 25mg/emtricitabine 200mg/ elvitegravir 150mg/cobicistat 150mg (Genvoya) once daily | 1 pill once daily | -Rapid drop in viral load  -Once daily dosing  -Lowest pill burden | Drug interactions (cobicistat a CYP3A4 inhibitor)  -possibility of Integrase inhibitor and nucleoside drug resistance with failure seen in trials |

**Anti-HIV Medications to Avoid Until Results of Resistance Testing, HLA-B5701 are Known:**

1. Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs): This class is most associated with transmitted drug resistance
2. Abacavir containing regimens: High risk of fatal abacavir hypersensitivity reaction if HLA-B5701+

**Resources for Clinicians:**

1. CCRMC HIV specialists:
   1. Judy Bliss 925-346-4286
   2. Larry Boly 925-346-4254
   3. Chris Farnitano 925-408-1547
   4. Jamie Pehling 925-346-4734
   5. Tony Pizzo 925-346-4102
2. HIV Warmline (UCSF HIV telephone consultation service) 8AM-5PM M-F: 800-933-3413
3. CCHS Public Health HIV/AIDS Program Main Number 925-313-6771
4. CCHS Public Health HIV AIDS Program Linkage to Care Manager- Karen Schlein 925-313-6783

1. Need reference to the study here [↑](#footnote-ref-1)
2. http://cchealth.org/aids/pdf/HIV-surveillance-brief2016.pdf [↑](#footnote-ref-2)
3. <http://www.gettingtozerosf.org/> -- *Not sure if this is where that data is located* [↑](#footnote-ref-3)
4. START INSIGHT Team NEJM 2015 [↑](#footnote-ref-4)
5. Jain et al. JID 2013; Saez-Ciron et al. VISCONTI team, PLoS Pathog. 2013 [↑](#footnote-ref-5)
6. HPTNO52-Cohen et al.NEJM 2011 [↑](#footnote-ref-6)
7. Oliver Bacon, MD, MPH, SF Dept. of Public Health [↑](#footnote-ref-7)